



HBsAg Fast Test Kit (Immunofluorescence Assay)

IF1064 for Getein 1100
IF5064 for Getein 1160
IF3064 for Getein 1180
IF4064 for Getein 1200
IF2064 for Getein 1600



Instructions for Use

INTENDED USE

HBsAg Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma samples. The test is used clinically as suitable for blood supply screening and clinical diagnosis of hepatitis B virus infection. For professional and laboratory use only.

SUMMARY

Hepatitis B is an infection of the liver caused by the Hepatitis B Virus (HBV). HBV is transmitted by exposure to infectious blood or body fluids (e.g. saliva, semen). Forms of transmission include unprotected sexual activity, blood transfusion, mother-to-infant transmission, or consuming contaminated food.

The average incubation period for HBV infection is 6 to 8 weeks (ranges from 1 to 6 months). Common clinical symptoms include malaise, fever, gastroenteritis, and icterus. In adults, 90% to 95% of patients with HBV infection completely recover from acute illness and clear the virus, approximately 5% to 10% of patients with HBV become chronic carriers. HBsAg is a coat protein of hepatitis B virus. It is composed of mixed polypeptides, containing lipids, sugars and proteins. It has strong resistance to low temperature and is not contagious itself. However, its appearance is often accompanied by the presence of hepatitis B virus, so it is a sign that it has been infected with hepatitis B virus. It can be present in the patient's blood, saliva, milk, sweat, tears, nasopharyngeal secretions, semen and vaginal secretions. It is estimated that over 300 million people worldwide are chronic carriers of the virus.

HBsAg usually appears 1 to 2 weeks after infection with

hepatitis B virus. Most patients with acute hepatitis B can turn negative in the early stage of the disease, and this indicator can be positive for patients with chronic hepatitis B. This kit is for the detection of HBsAg and is suitable for blood supply screening and auxiliary diagnosis of clinical hepatitis B virus infection. HBsAg is observed in persons with acute and chronic hepatitis B infections.

PRINCIPLE

HBsAg Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence-labelled HBsAg monoclonal antibody binds with the HBsAg in sample and forms marked antigen-antibody complex. This complex moves to the detection zone on the test card by capillary action and is captured by another HBsAg monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HBsAg in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the HBsAg in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
HBsAg test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	/	/	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*HBsAg test card

A test card mainly consists of: Fluorescence-labelled HBsAg monoclonal antibody and HBsAg monoclonal antibody.

**Sample diluent

(1) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

- Phosphate buffer (20 mmol/L), NaN₃ (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box)

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card or pipet.
6. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum and plasma samples**.
2. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma samples.
3. It is recommended to test the sample within 4 hours after collection. If testing is delayed, serum and plasma samples are stable for 5 days when stored at 2~8°C and 6 months when stored at -20°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 µL.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- 1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
- 4) Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- 5) Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- 1) Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch immediately



Getein Biotech, Inc.
 Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
 Tel: +86-25-68568508
 Fax: +86-25-68568500
 E-mail: tech@getein.com.cn
 overseas@getein.com.cn
 Website: www.getein.com

before use and put the test card on a clean table, horizontally placed.

- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Put the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

- It is required to perform “SD card” calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
- Make sure the insertion of test card and the sample are correct and complete.

RESULTS

- Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.
- Samples with concentration <1.00 IU/mL are considered negative and no further testing is required.
- Samples with concentration ≥1.00 IU/mL are considered positive. All positive samples that are initially tested should be retested twice. If both retests are negative, the sample must be considered HBsAg negative. If any of the retest values is positive, it is considered HBsAg positive.
- Due to different methodologies or antibody specificity, there may be deviations between the test results of different

manufacturers, so they can't be compared directly.

- Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 80 times.

LIMITATIONS

As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

EXPECTED VALUE

The expected normal value for HBsAg was determined by testing samples from 460 apparently healthy individuals. The reference range of HBsAg is 1.00 IU/mL calculated by using normal distribution methods giving a level of confidence of approximately 99%.

It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

- | | |
|--------------------------|-------------------|
| 1. Measuring Range | 1.00~100.00 IU/mL |
| 2. Limit of Detection | ≤1.00 IU/mL |
| 3. Within-Run Precision | ≤10% |
| 4. Between-Lot Precision | ≤15% |

REFERENCES

- Godoy BA, Gomes-Gouvea MS, Zagonel-Oliveira M, et al. High prevalence of HBV/A1 subgenotype in native south Americans may be explained by recent economic developments in the Amazon. *Infection Genetics and Evolution* 2016, 43: 354-363.
- Nguyen LH, Hoang J, Nguyen NH, et al. Ethnic differences in incidence of hepatitis B surface antigen seroclearance in a real-life multicenter clinical cohort of 4737 patients with chronic hepatitis B infection. *Alimentary Pharmacology & Therapeutics* 2016, 44(4): 390~399.
- Ork V, Woodring J, Shafiqul MD, Annemarie H, et al. Hepatitis B surface antigen seroprevalence among pre- and

- post-vaccine cohorts in Cambodia, 2017 *Vaccine*, 2019, 37(35).
- Mathias EE, Mbouamba YB, Esemu S, et al. The prevalence of HBsAg, knowledge and practice of hepatitis B prevention among pregnant women in the Limbe and Muyuka Health Districts of the South West region of Cameroon: a three-year retrospective study. *The Pan African medical journal*, 2019, 32.
- Cai QY, Liu HY, Han WH, et al. Maternal HBsAg carriers and adverse pregnancy outcomes: A hospital-based prospective cohort analysis. *Journal of viral hepatitis*, 2019, 26(8).
- Chen L, Shi JJ, Lu ZH, et al. Baseline HBsAg levels associated with HBsAg loss in HBeAg-negative chronic hepatitis B infection with persistently normal alanine aminotransferase. *Clinics and Research in Hepatology and Gastroenterology*, 2019, 43(3).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on HBsAg Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for >n tests		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using HBsAg Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.